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1 of 2

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APPENDIX E

510(k) SUMMARY
Robin Hood Vest™
Kamber Corporation

This 510(k) summary of safety and effectiveness for the Robin Hood Vest™ is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Kamber Corporation
Address:	104 S. 16th Street San Jose, CA 95112
Contact Person:	Connie DeWitt President
Telephone:	(408) 286-6956 (telephone) (408) 228-8423 (fax)
Preparation Date:	May 2005
Device Trade Name:	Robin Hood Vest™
Common Name:	Pediatric Position Holder
Classification Name:	Pediatric Position Holder (see 21 C.F.R. § 880.5680) Product Code: FRP
Predicate Device:	Nightform -- 510(k) # K041996
Device Description:	The Robin Hood Vest™ is a sleeveless vest, with a pocket on the back for an insertable foam wedge, that an infant wears while sleeping. The device positions a foam wedge under the infant during sleep to direct the head so that it does not always rest on the same spot.
Intended Use:	The Robin Hood Vest™ is intended for use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.
CONCLUSIONS:	Based on the foregoing and other information in this application, Kamber Corporation believes that the Robin

Hood Vest is substantially equivalent to its claimed predicate under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 8 2005

Kamber Corporation
C/O Mr. David J. Bloch
ReedSmith
1301 K Street, North West
Suite 1100-East Tower
Washington, D.C. 20005-3373

Re: K051300
Trade/Device Name: Robin Hood Vest™
Regulation Number: 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: I
Product Code: FRP
Dated: October 31, 2005
Received: November 1, 2005

Dear Mr. Bloch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

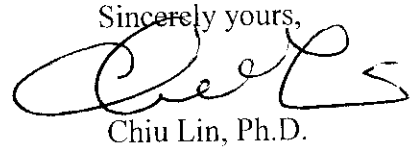
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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TAB C

510(k) Number: K051300

Device Name: Robin Hood Vest™

INDICATIONS FOR USE:

The Robin Hood Vest™ is intended for use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.

* * *

Prescription Use _____ OR Over-the-Counter Use ___X___

(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

William M. Burdick
for Anthony D. Watson 12/7/05

Division of General Hospital
Infection Control, Dental Devices

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